

Tall Pines Park
Jaffrey, NH 03452
532-7706
FAX (603) 532-8211

510(k) Summary

K9645-75
P172

1. Submitter Name, Address, and Date of Submission:

Miss Karenann J. Brozowski
Group Regulatory Affairs Director
Rüsch International
Tall Pines Park
Jaffrey, NH 03452

FEB - 4 1997

Telephone: (603)532-7706

Contact: Same as above.

2. Names of the Device, Common, Proprietary(if Known), and Classification.

Classification Name: Urological Catheter, Retention Type, Balloon

Proprietary Name: Rüsch SympaCath™ Hydrogel Coated Foley Catheter

Common Name: Foley Catheter

3. Identification of the legally marketed device to which the submitter claims equivalence.

The Rüsch International Hydrogel Coated Foley Catheter is equivalent to the Bard Biocath and Lubricath or the Curity Kendall Ultramer coated catheters.

4. Description of the Device:

The Rüsch SympaCath Hydrogel Coated Foley Catheter is a standard foley catheter, which has been coated with a coating known as hydrogel. The purpose of the coating is to make the catheter slippery on insertion, post activation with water.

page 2

5. Intended Use of the Device:

This device is a urological catheter, which is a tubular device that is inserted through the urethra and is used to pass fluids to or from the urinary tract.

6. Summary of Technological Characteristics:

The following technological characteristics are the same or equivalent as predicate devices:

The coating is added to a standard foley catheter.

The coating is activated with contact with water, making the catheter slippery to ease insertion.

The design, material construction and principals of operation for the SimpaCath Hydrogel Foley Catheters are the same as the competitors.

sumhcl